

§ 524.1200

against eggs and immature stages has not been proven.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[66 FR 7578, Jan. 24, 2001]

§ 524.1200 Kanamycin ophthalmic and topical dosage forms.

§ 524.1200a Kanamycin ophthalmic ointment.

(a) *Specifications.* The drug, which is in a suitable and harmless ointment base, contains 3.5 milligrams of kanamycin activity (as the sulfate) per gram of ointment.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* It is indicated for use in dogs in various eye infections due to kanamycin sensitive bacteria. It is used treating conditions such as conjunctivitis, blepharitis, dacryocystitis, keratitis, and corneal ulcerations and as a prophylactic in traumatic conditions, removal of foreign bodies, and intraocular surgery. Apply a thin film to the affected eye three or four times daily or more frequently if deemed advisable. Treatment should be continued for at least 48 hours after the eye appears normal. For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 53 FR 27851, July 25, 1988; 64 FR 404, Jan. 5, 1999]

§ 524.1200b Kanamycin ophthalmic aqueous solution.

(a) *Specifications.* The drug, which is in an aqueous solution including suitable and harmless preservatives and buffer substances, contains 10 milligrams of kanamycin activity (as the sulfate) per milliliter of solution.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* It is indicated for use in dogs in various eye infections due to kanamycin sensitive bacteria. It is used in treating conditions such as conjunctivitis, blepharitis, dacryocystitis, keratitis, and corneal ulcerations and as a prophylactic in traumatic conditions, removal of foreign bodies, and intraocular surgery. Instill a few drops into the affected eye every 3 hours or more frequently if deemed advisable. Administer as fre-

21 CFR Ch. I (4-1-05 Edition)

quently as possible for the first 48 hours, after which the frequency of applications may be decreased. Treatment should be continued for at least 48 hours after the eye appears normal. For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 53 FR 27851, July 25, 1988; 64 FR 404, Jan. 5, 1999]

§ 524.1204 Kanamycin sulfate, calcium amphomycin, and hydrocortisone acetate.

(a) *Specifications.* (1) Calcium amphomycin is the calcium salt of amphomycin. It conforms to the following specifications:

(i) Its potency is not less than 863 micrograms of amphomycin per milligram;

(ii) Its moisture content is not more than 10 percent; and

(iii) Its pH in a 2-percent aqueous suspension is 6.0 to 7.5.

(2) The drug is in a water-miscible ointment or cream base and each gram of ointment or cream contains: 5.0 milligrams of kanamycin activity as the sulfate, 5.0 milligrams of amphomycin activity as the calcium salt, and 10.0 milligrams of hydrocortisone acetate.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is indicated for use in dogs in the following conditions associated with bacterial infections caused by organisms susceptible to one or both antibiotics: Acute otitis externa, furunculosis, folliculitis, pruritus, anal gland infections, erythema, decubital ulcer, superficial wounds, and superficial abscesses.

(2) The ointment should be applied to the affected areas of the skin at least twice daily. In severe or widespread lesions it may be desirable to apply the ointment more than twice daily. After some improvement is observed, treatment can usually be reduced to once daily. Before application, hair in the affected area should be closely clipped and the area should be thoroughly cleansed of crusts, scales, dirt, or other detritus. When treating infections of the anal gland, the drug should be introduced into the orifice of the gland and not through any fistulous tract. If